

Congress of the United States
Washington, DC 20515

April 27, 2020

Christi A. Grimm
Principal Deputy Inspector General
Office of Inspector General
Department of Health and Human Services
330 Independence Avenue, SW
Washington, DC 20201

Dear Ms. Grimm:

We write to request your attention to the U.S. Food and Drug Administration's (FDA) decision to grant an emergency use authorization (EUA) for hydroxychloroquine and chloroquine to treat COVID-19 in light of renewed focus on the agency's decision. We first wrote to the FDA on April 8 regarding the EUA for hydroxychloroquine and chloroquine as well as the approval for a clinical trial of a stem cell therapy for the treatment of COVID-19. While we do not criticize the therapies themselves, recent events heighten our alarm that the FDA's decision-making process to expand their use in the fight against COVID-19 was potentially compromised by political pressure.

On April 22, the Director of the U.S. Biomedical Advanced Research and Development Authority (BARDA), Dr. Rick Bright, was removed from his post. According to Dr. Bright, he was dismissed after he actively resisted "efforts to fund potentially dangerous drugs promoted by those with political connections" during an urgent public health crisis.¹ Internally, Dr. Bright questioned the use of unproven therapies on COVID-19 patients and asked the U.S. Department of Health and Human Services (HHS) Office of the Inspector General (OIG) to investigate "the manner in which this administration has politicized the work of BARDA and has pressured [Bright] and other conscientious scientists to fund companies with political connections and efforts that lack scientific merit."² In light of Dr. Bright's whistleblowing request to the OIG and his subsequent removal from BARDA, we now request a formal investigation into the FDA's granting of an EUA for hydroxychloroquine and chloroquine.

It is significant that FDA officials have also questioned the EUA. Their conclusions are established from a documented lack of scientific evidence that hydroxychloroquine and chloroquine are beneficial in the treatment of COVID-19, as well as established precedent that an EUA should only be issued when the evidence indicates that benefits outweigh the risks.³ We therefore request that you investigate the consequences arising from the non-scientific promotion of hydroxychloroquine and chloroquine as therapeutic options for COVID-19 patients by the federal government, its agents, and officials outside of the government. Specifically, we ask that you investigate the following points:

- 1) Any FDA actions outside of the agency's standard processes to grant hydroxychloroquine and chloroquine an EUA (i.e. approving an EUA for a drug manufactured in an overseas plant that was never inspected by the FDA).
- 2) Any undue political pressure from administration staff upon career health officials to make hydroxychloroquine and chloroquine available.
- 3) Any fraudulent behavior by providers who rushed to use their prescription authority to acquire hydroxychloroquine and chloroquine, causing shortages for Americans who take these medications regularly for autoimmune diseases like rheumatoid arthritis and lupus.
- 4) The circumstances of Dr. Bright's reassignment and whether his criticism of pushing an unproven drug for the treatment of COVID-19 was the cause of his removal from BARDA.
- 5) Administration officials' push for hydroxychloroquine and chloroquine being widely available outside of inpatient hospital settings. Specifically, did administration officials push physicians in advance to prescribe chloroquine drugs for the treatment of COVID-19, and did administration officials have a plan for Risk Evaluation Mitigation Strategies (REMS) to monitor individuals taking chloroquine drugs prescribed by physicians?

Statements promoting a therapy with no evidence, combined with the FDA's issuance of an EUA outside of its standard process, have given many Americans false hope at a precarious moment, causing them to believe that these experimental drugs are a cure-all for this pandemic. Since the administration's actions, a large analysis of hydroxychloroquine in COVID-19 patients in U.S. veterans' hospitals showed no benefit and even noted that there were more deaths among those given hydroxychloroquine versus standard care.⁴ Furthermore, in demoting Dr. Bright because he was skeptical of the science behind the decades-old malaria drug to treat COVID-19, the administration is sidelining one of the nation's leading experts in vaccine development at a time when we are rushing to develop a vaccine to prevent COVID-19. We are heartened by the FDA's official statement on April 24 deterring hydroxychloroquine outside of hospitals, but our government must go much further to assure public confidence and health.⁵

As our nation continues to grapple with COVID-19, both the untainted operation of our medical institutions and the American public's full trust in those institutions must be unimpeachable and beyond reproach. Without swift investigation into whether the government has placed politics over science, both may be in hazard. We look forward to your response.

Sincerely,



Bill Pascrell, Jr.
Member of Congress



Robert Menendez
United States Senator

¹ Florko, N. (2020). An ousted vaccine agency director offers an explosive, direct allegation: Trump is politicizing science. Retrieved from [https://www.statnews.com/2020/04/22/rick-bright-allegations-politicize-science/?utm_source=STAT+Newsletters&utm_campaign=01d43bb169-](https://www.statnews.com/2020/04/22/rick-bright-allegations-politicize-science/?utm_source=STAT+Newsletters&utm_campaign=01d43bb169-MR_COPY_01&utm_medium=email&utm_term=0_8cab1d7961-01d43bb169-149591869)

[MR_COPY_01&utm_medium=email&utm_term=0_8cab1d7961-01d43bb169-149591869](https://www.statnews.com/2020/04/22/rick-bright-allegations-politicize-science/?utm_source=STAT+Newsletters&utm_campaign=01d43bb169-MR_COPY_01&utm_medium=email&utm_term=0_8cab1d7961-01d43bb169-149591869)

² Young, D. (2020). Ex-BARDA chief says political dispute over unproven COVID-19 drugs led to ouster.

Retrieved from <https://www.spglobal.com/marketintelligence/en/news-insights/latest-news-headlines/ex-barda-chief-says-political-dispute-over-unproven-covid-19-drugs-led-to-ouster-58155765>

³ Eban, K. (2020). “Really want to flood NY and NJ”: Internal documents reveal team trump’s chloroquine master plan. Retrieved from <https://www.vanityfair.com/news/2020/04/internal-documents-reveal-team-trumps-chloroquine-master-plan>

⁴ Marchione, M. (2020). More deaths, no benefit from malaria drug in VA virus study. Retrieved from <https://apnews.com/a5077c7227b8eb8b0dc23423c0bbe2b2>

⁵ Center for Drug Evaluation and Research. (2020). FDA cautions against use of hydroxychloroquine or chloroquine for COVID-19 outside of the hospital setting or a clinical trial due to risk of heart rhythm problems. Food and Drug Administration, Retrieved from <https://www.fda.gov/drugs/drug-safety-and-availability/fda-cautions-against-use-hydroxychloroquine-or-chloroquine-covid-19-outside-hospital-setting-or>